Ancare New Zealand Ltd
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23 August 2004

Dr. Lonnie Luther
Quality Assurance Support Team (HFV-102) Room 387
FDA Center for Veterinary Medicine
7500 Standish Place
Rockville, MD 20855

Dear Dr. Luther,

Please find enclosed a suitability petition submitted on behalf of Ancare New Zealand Limited of New Zealand. Ancare requests consideration of this suitability petition to file an ANADA for a different concentration and presentation (ready to use solution) of Levamisole Hydrochloride for cattle and sheep.

Please call if you have questions.

Sincerely,

Robert Holmes
Business Development Manager
Ancare New Zealand Ltd.

2004P-0384

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SUITABILITY PETITION

IDENTIFICATION OF PETITIONER:

This Suitability Petition is submitted on behalf of Ancare New Zealand Limited of New Zealand under Section 512 (n)(3) of the Federal Food, Drug, and Cosmetic Act.

ACTION REQUESTED:

The petitioner requests permission from the Commissioner to file an Abbreviated New Animal Drug Application (ANADA) for a different concentration and presentation of an approved pioneer product. The pioneer product is Schering Plough's LEVASOLE® (levamisole hydrochloride) Soluble Drench Powder, approved by the Food and Drug Administration under NADA #112-051. A copy of the pioneer product labeling is provided (**Attachment 1**).

The ANADA will provide for levamisole hydrochloride in a stable, ready to use aqueous solution containing 159.7 mg levamisole hydrochloride per mL rather than the 544.5 grams levamisole hydrochloride powder for reconstitution found in the pioneer product. Both the proposed generic and the pioneer products are delivered orally as an aqueous solution to affected animals at the rate of 3.63 mg levamisole hydrochloride per pound of body weight for the effective control of the listed parasites.

The product labeling will provide for indications, recommended dosages, and precautions identical to the pioneer product. Draft labeling for the proposed product is provided (**Attachment II**).

The proposed product label will differ from the pioneer product specifically as follows:

1) The generic product label will refer to 159.7 mg/mL levamisole hydrochloride in a ready to use solution rather than 544.5g of powder for reconstitution in 3 liters of water (final concentration of 181.5 mg/mL) at the time of use.
2) For cattle, the dosage instructions will recommend 2.5 mL for each 110 pounds of body weight rather than 2 mL for each 100 pounds. For sheep, the dosage instructions will recommend 1mL for each 44 pounds of body weight rather than 1 mL for each 50 pounds.
3) The container types and net contents of the containers may differ from the pioneer product. Actual containers are yet to be determined.
4) Instructions for mixing are removed. There will be no need for mixing of the product by the end user.

STATEMENT OF GROUNDS:

The proposed product contains the same active ingredient and will be labeled with the same indications, recommended dose rates, contraindications, precautions and warnings as the approved pioneer product. Because the same amount of active drug will be delivered orally, the clinical effect for both drugs is expected to be similar.

ENVIRONMENTAL IMPACT:

The action of submitting this Suitability Petition and its review by the FDA - Center for Veterinary Medicine is not expected to have an environmental impact. The action requested qualifies for categorical exclusion under 21 CFR Part 25.30(h) from the requirement for an environmental assessment and, to the best of the sponsor's knowledge, no extraordinary circumstances exist.

ECONOMIC IMPACT:

An "Economic Impact" analysis of this action will be provided if requested by the Commissioner.

CERTIFICATION:

Ancare New Zealand Limited certifies that this suitability petition contains all information known to them which is unfavorable to the petition.

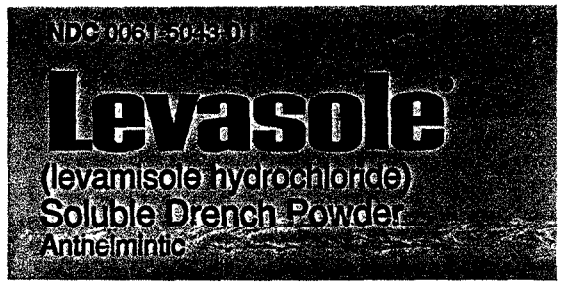
08/23/04
Date

Robert Holmes
Business Development Manager
Ancare New Zealand Ltd.
First Floor, 17 Shea Terrace
Takapuna, Auckland
PO Box 36240, Northcote
Auckland, New Zealand

Attachments

1. Pioneer Product Label
2. Proposed Product Label

ATTACHMENT 1
Pioneer Product Labeling



Cattle and Sheep Dewormer For Oral Use

This bottle contains 544.5 grams of levamisole hydrochloride activity.

INDICATIONS: LEVASOLE (levamisole hydrochloride) is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle and sheep:

STOMACH WORMS: *(Haemonchus, Trichostrongylus, Ostertagia)*

INTESTINAL WORMS: *Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum)* [*Chabertia* Sheep only]

LUNGWORMS: *(Dictyocaulus)*

TAKE TIME
OBSERVE LABEL DIRECTIONS

WARNING: Keep out of reach of children.

Net Wt. 21.34 oz (1.3 lb)
(605 g)

Schering-Plough
Animal Health

LOT 018771
EXP 06/2005

Schering-Plough Animal Health Corp.
Union, NJ 07083
Made in Ireland

NADA #112-051, Approved by FDA.

NDC 0061-5043-01 1

DOSAGE AND ADMINISTRATION: When you are ready to deworm your cattle or sheep, add water to the powder in this bottle up to the 3 liter mark. Swirl to mix thoroughly before using. If any solution is left over it may be stored for up to 3 months in this tightly capped bottle. Shake well before using.

DATE WATER
WAS ADDED
TO THIS BOTTLE Month Day Year

Administer as a single drench dose as follows:

CATTLE – 2 mL per 100 lb. body weight

Weight	Drench Dosage	Bottle Will Treat
100 lb	2 mL	1,500 head
300 lb	6 mL	500 head
500 lb	10 mL	300 head
700 lb	14 mL	214 head
1,000 lb	20 mL	150 head

SHEEP – 1 mL per 50 lb. body weight

Weight	Drench Dosage	Bottle Will Treat
50 lb	1 mL	3,000 head
100 lb	2 mL	1,500 head
150 lb	3 mL	1,000 head
200 lb	4 mL	750 head

NOTE: Careful weight estimates are essential for proper performance of this product.

Cattle and Sheep maintained under conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment.

WARNING: Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

CAUTION: Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

 20470208 Rev 8/97

ATTACHMENT 2
Proposed Generic Product Label

ANADA XXX-XXX, Approved by FDA

TRADENAME (levamisole hydrochloride) Solution

Anthelmintic

Ready to use Cattle and Sheep Dewormer for Oral Use

Contains 159.7 mg levamisole hydrochloride/mL in a ready to use formulation.

Indications

TRADENAME (levamisole hydrochloride) is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle and sheep:

Stomach Worms – *(Ostertagia, Haemonchus, Trichostrongylus)*
Intestinal Worms – *(Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum,* [*Chabertia* - sheep only]
Lungworms – *(Dictyocaulus)*

Warning: Keep this and all drugs out of the reach of children.

Dosage and Administration:

Administer as a single drench dose as follows:
Cattle: The dose rate is 2.5 mL for each 110lb (50kg) of body weight.

Weight	Dose	Bottle will treat*
110lbs	2.5mL	
220lbs	5.0mL	
330lbs	7.5mL	
440lbs	10.0mL	
550lbs	12.5mL	
660lbs	15.0mL	
770lbs	17.5mL	
880lbs	20.0mL	
990lbs	22.5mL	
1,100lbs	25.0mL	

Sheep: The dose rate is 1.0mL for each 44lb of bodyweight.

Weight	Dose	Bottle will treat*
44lbs	1.0mL	
66lbs	1.5mL	
88lbs	2.0mL	
110lbs	2.5mL	
132lbs	3.0mL	

** (TO BE INSERTED BASED ON CONTAINER SIZE CHOSEN)*

Note: Careful weight estimates are essential for proper performance of this product.

Cattle and sheep maintained under conditions of constant helminth exposure may require retreatment within two to four weeks after the first treatment.

Warning: Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

Caution: Muzzle foam may be observed. However this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism .